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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,488	05/25/2001	Anthony E. Bolton	033136-179	4401

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EXAMINER
YU, MISOOK

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,488	BOLTON ET AL.	
	Examiner	Art Unit	
	Misook Yu	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on May 25, 2000. It is noted, however, that applicant has not filed a certified copy of the 2,309,518 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-18 recite "apoptotic bodies" and "apoptotic cells." But it is not clear what the bounds are for "apoptotic bodies" and "apoptotic cells". What are the differences between the two. The specification at page 2 lines 7-10 says "Following these morphological changes, an apoptotic cell may break-up into a number of small fragments known as apoptotic bodies comprising membrane-bound bodies containing intact organelles, chromatin, etc." If "apoptotic bodies" are fragment of "apoptotic cell", how could fragment is still bound by membrane. What is fragmented to make apoptotic bodies? Is there any distinction between dying cells and the apoptotic cells of the instant invention? fixed

Claims 1-18 provides for the use of apoptotic bodies" and/or "apoptotic cells, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. fixed

Claims 1-18 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1, 2, and 15 recite "T-cell mediated and inflammatory disorders" but it is not clear what the metes and bounds are for "T-cell mediated and inflammatory disorders".

Claim 3 and 4 recite "cellular." Dorland Pocket Medical Dictionary defines "cellular" as "pertaining to or composed of cells." If apoptotic bodies are fragments of apoptotic cells, apoptotic bodies do not belong to cellular portion.

Claim 6 recites "extracorporeal treatment," but it is not clear what the metes and bound are for extracorporeal extracorporeal treatment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for how to make and use the apoptotic bodies and/or apoptotic cells made from mice fibroblasts for treatment of mice contact hypersensitivity, one of T-cell-mediated and inflammatory disorders in a mammalian patients (Figure, and Example 1 and 2 of the specification), does not reasonably provide enablement for use of the instant invention in treatment and/or prophylaxis of any other T-cell-mediated and inflammatory disorders in mammalian patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claims 1-18 are drawn to the use of the various compositions of apoptotic bodies and/or apoptotic cells in treatment and/or prophylaxis for T-cell-mediated and inflammatory

disorders in mammalian patients. As for the problem with how to make the invention, the teachings of the specification are limited to how to make the apoptotic cells and/or apoptotic bodies from murine fibroblasts with sodium butyrate and UV (page 13, lines 16-17), none of the sources cited in claims 7-10. It is noted that the specification does not teach if the donor and recipient fibroblasts are same or the fibroblasts are from a established cultured cell line (claim 7). Although inducing apoptosis in mammalian cells are known in the art as listed at page 7, last two lines to page 8 of the specification, the specification fails to teach what is appropriate choice and treatment of cells to make the appropriate apoptotic cells and/or apoptotic bodies for each diseases listed in claim 11 or any other T-cell-mediated and inflammatory disorders at page 12, lines 14-24 and other possible T-cell-mediated and inflammatory disorders. As for the problem with how to use the invention in the treatment and/ or prophylaxis of -cell-mediated and inflammatory disorders, teaching of the instant specification is limited to mice contact hypersensitivity. The factors which must be considered in determining undue experimentations are set forth in In re Wands USPOQ2d 1400. The factors include 1) quantity of experimentation necessary, 2) the amount of guidance presented, 3) the presence or absence of working example, 4) the nature of the invention, 5) the state of the prior art, 6) the predictability of the art, 7) breath of the claims. With regard to factors 1) and 2) above undue experimentation is required to determine how to make and use the claimed invention (claims 1-18) for each of the disease listed in claim 11 because the only guidance provided in the specification for making the invention is "appropriate levels of treatment of the cells to create apoptotic bodies for use in the present invention depend to some extent on the nature of the chosen cells and cellular composition, and the type of treatment chosen to induce apoptosis" at page 9 lines 14-19 of the specification and only guidance provided in the specification for using the instant invention is "the specific dose employed will, of course, be dependent upon the age, weight and severity of the disease in the treated patient all of which are within the skill of the attending clinician" at page 11, last line at page 12, lines 1 and 2. There is no evidence that the range specified in claim 4, 5, 12-14, and 16-18 are useful range of treating and/or preventing any disease listed in the claims 11. It is noted that use of

apoptotic cells and/or apoptotic bodies is not accepted treatment for any diseases listed in the claim 11 or any other T-cell-mediated and inflammatory disorders in mammalian patients. Therefore, arguing that the determination of the specific dosage is within the skill of the attending clinician is not persuasive. It might take years through lengthy clinical trials for research clinicians to determine (1) which source of the cells to make apoptotic cells and/or apoptotic bodies for each of specific diseases, (2) a specific dose for any one of the diseases listed in claim 11. Many of the diseases listed in claim 11 are notoriously difficult to treat, and therefore those skilled in the art would have reason to doubt unsupported assertions of successful treatment methods for those diseases. With regard to factors 4), 5), and 6) above, there is a great deal of unpredictability in the treatment and/or prophylaxis of diseases in claim 11 because the precise mechanism of the diseases listed in claim 11 is not well understood (Lui et al). It is noted that law requires that the disclosure of an application shall inform those skilled in the art how to use applicants' alleged discovery, not how to find out how to use it for themselves. With factors 3) and 7) above it is noted that no working example is present to indicate that claimed invention could be used in any of the disease listed in the claim 11. With regard to factor 5) above, the closest prior art is U.S. Patent 5,980,954 (IDS). U.S. Patent 5,980,954 describes process of generating "autovaccine" (column 4, line 65) to be used to alleviate the symptoms of an autoimmune disease.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 09/866,569. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn in part to treatment of inflammatory bowel disease, atherosclerosis, and graft versus host disease with apoptotic bodies and/or cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
February 19, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600

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